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10/559,547	01/13/2006	Joachim Hoernes	007404-001084 21731 US	9151
41577 7590 09/30/2010 Woodard, Emhardt, Moriarty, McNett & Henry LLP Roche Diagnostics 111 Monument Circle, Suite 3700 Indianapolis, IN 46204-5137				
EXAMINER				
TOTI, KAREN E				
ART UNIT		PAPER NUMBER		
3735				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/559,547

Applicant(s)

HOENES ET AL.

Examiner

KAREN E. TOTH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-47 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 25-47 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Objections

1. Claim 28 is objected to because of the following informalities: Line 12 recites "element is extends within the lancet". For the purposes of examination this will be treated as though reading "element extends within the lancet".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 6 of claim 25 refers to "a second proximal end", but no first proximal end is ever defined. It appears that the claim is directed to first and second ends of an element, where the first end is distal and the second end is proximal. For the purposes of examination, the claim will be treated as though line 6 reads "a proximal end".

Line 7 of claim 28 refers to "the second end", but no element is defined as a second end. For the purposes of examination the claim will be treated as though reading "the proximal end".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 25, 28, 34, 35, 37-41, and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Coleman (US 4622974).

Regarding claim 25, Coleman discloses a system for analyzing a sample comprising a test field with a reagent which, on contact, interacts with an analyte contained in a sample resulting in an optically detectable change in the test field (column 7, lines 53-68), a light-conducting element with a distal end on which the test field is coated (element 16 - figures 1 and 1a) and a proximal end into which light may be coupled (element 14) and which can conduct light away again from the test field (column 4, lines 42-66), and a lancet at least partially surrounding the light-conducting element (figure 1a) having a tip located in a region of the distal end and test field (element 19; figures 1, 1a) such that, during a lancing process, the lancet tip extends beyond the distal end of the light-conducting element and the test field (figure 1a), and wherein the lancet has an opening that enables the test field on the distal end of the light-conducting element to protrude beyond the lancet tip for contacting the sample (at end 19, shown best in figure 1a). The Examiner notes that, though Coleman does not explicitly disclose the light-conducting element extending beyond the end of the lancet, the opening

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enables it to do so. The Examiner also notes any two components of the same invention may be reasonably considered to be "in a/the region of" each other.

The Examiner also notes that "to coat" is defined by Merriam-Webster as "to cover or spread with a finishing, protecting, or enclosing layer", and the reagent entrapped in the sample cavity 36 covers the distal end of the light-conducting element.

Regarding claim 28, Coleman discloses a system for analyzing a sample comprising a test field containing a reagent which, on contact, interacts with an analyte contained in a sample resulting in an optically detectable change in the test field (column 7, lines 53-68), a light-conducting element with a distal end permanently connected to the test field (element 16; figures 1 and 1a; the test field is defined by the end of the light-conducting element, making them permanently connected) and a proximal end into which light can be coupled (element 14) such that light is conducted from the proximal end to the test field and is conducted away again from the test field by the same or another light-conducting element (column 4, lines 42-66), and a lancet having a lancet tip (element 19) located in a region of the distal and of the test field such that the lancet tip extends beyond the distal end of the light guide and test field during a lancing process (figure 1a), wherein the light-conducting element extends within the lancet (figure 1, 1a), wherein the lancet has an opening that enables the test field on the distal end of the light-conducting element to protrude beyond the lancet tip for contacting the sample (at end 19, shown best in figure 1a). The Examiner notes that, though Coleman does not explicitly disclose the light-

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conducting element extending beyond the end of the lancet, the opening enables it to do so.

Regarding claims 34 and 35, Coleman's light-conducting element is surrounded by and concentrically within the lancet, which is hollow (figure 1a); the concentric positioning puts the element and lancet in direct vicinity to one another in the plane perpendicular to the lancing direction.

Regarding claim 37, since Coleman's system is configured for determining concentrations of any desired component in a body fluid, it is suitable (able, qualified) for determining a glucose concentration.

Regarding claim 38, Coleman further discloses the system being optically contacted with an analytical unit of an analytical instrument such that light is coupled into or out of the light-conducting element (column 4, lines 42-66).

Regarding claim 39, since the system performs lancing (to pierce with or as if with a lance), it is therefore part of a lancing device.

Regarding claims 40 and 41, Coleman further discloses the system being optically contacted with an analytical unit of an analytical instrument such that light is coupled into or out of the light-conducting element (column 4, lines 42-66).

Regarding claim 44, Coleman further discloses a drive unit for the light-conducting element (element 40).

Regarding claims 45 and 46, Coleman further discloses a drive unit for transporting the test element (element 26).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman and further in view of Riccitelli (US 5054882).

Regarding claims 26 and 32, Coleman discloses all the elements of the claimed invention, as described above, except for the system comprising a plurality of test fields. Riccitelli teaches a system for analyzing a sample using a sensor inserted through an introducer where the sensor component has a plurality of individual sensors (elements 14a, 14b, 14c) within its introducing sheath (figure 1), in order to allow simultaneous sensing of multiple body constituents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Coleman with a plurality of light-conducting elements/test fields (sensors), as taught by Riccitelli, in order to allow simultaneous sensing of multiple body constituents.

8. Claims 27, 36, 42, 43, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman in view of Kuhr (US 7396334).

Regarding claim 27, Coleman discloses all the elements of the claimed invention, as described above, except for the system having a plurality of lancets.

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Kuhr teaches a system for analyzing a sample where the system comprises a plurality of lancets (figure 6), in order to allow testing to be performed a plurality of times. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Coleman with a plurality of lancets, as taught by Kuhr, in order to allow testing to be performed a plurality of times.

Regarding claim 36, Kuhr further teaches the lancet tip being embedded in a sterile protection prior to insertion (column 6, lines 12-19), in order to prevent contamination. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Coleman with the lancet tip embedded in a sterile protection prior to insertion, as taught by Kuhr, in order to prevent contamination.

Regarding claim 42, Coleman does not disclose how the lancet is inserted. Kuhr teaches a teaches a system for analyzing a sample where the system comprises a teaches a system for analyzing a sample where the system comprises a lancet configured to be inserted by a drive unit in a lancing device (column 6, lines 1-8), in order to ensure an uninterrupted insertion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Coleman with a drive unit for the lancet, as taught by Kuhr, in order to ensure an uninterrupted insertion.

Regarding claim 43, Coleman, as modified by Kuhr as applied to claim 42 above, further discloses a drive unit for the light-conducting element (element 40).

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Regarding claim 47, Coleman discloses all the elements of the claimed invention, as described above, except for the system being in a magazine of the lancing device with a plurality of such systems. Kuhr teaches a system for analyzing a sample where the system contains a plurality of lancing devices in a magazine (figure 6), in order to allow testing to be performed a plurality of times. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Coleman with a plurality of the systems (the lance/conducting element combination, structurally equivalent to Kuhr's lance) in a magazine, as taught by Kuhr, in order to allow testing to be performed a plurality of times.

9. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman, as applied above, and further in view of Garcia (US 4627445).

Coleman discloses using a reagent, but does not specifically disclose whether any interactions are reversible or irreversible; Coleman also discloses that any desired reagent may be used, depending on the analyte to be sampled. Garcia teaches using a reagent to analyze a sample, where the reagent's interaction with the analyte sample is essentially irreversible (column 7 line 14 to column 8 line 34), in order to achieve a desired reaction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Coleman with a reagent configured to react essentially irreversibly with the analyte, as taught by Garcia, in order to achieve a desired

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reaction. The Examiner notes that, because the reaction is essentially irreversible, the system is therefore suitable only for single use.

10. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman in view of Riccitelli, as applied above, and further in view of Kuhr.

Regarding claim 33, Coleman in view of Riccitelli discloses all the elements of the claimed invention, as described above, except for the system having a plurality of lancets. Kuhr teaches a system for analyzing a sample where the system comprises a plurality of lancets (figure 6), in order to allow testing to be performed a plurality of times. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Coleman as modified by Riccitelli with a plurality of lancets, as taught by Kuhr, in order to allow testing to be performed a plurality of times.

Response to Arguments

11. Applicant's arguments filed 29 June 2010 have been fully considered but they are not persuasive.

Applicant has argued that, because Coleman's reagent is contained within a cavity, it is not "coated" on the distal end of the light-conducting element. The Examiner disagrees. As noted above, to coat is merely to cover. Since the reagent chamber is immobilized at the distal end of the light conducting element, some portion of the distal end must have the test field coated thereon. Applicant also argues that coating the end of the Coleman's light-conducting element would

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render it inoperable. This is certainly not found persuasive, as Coleman explicitly states that the test field (chamber with immobilized reagent) is at the distal end of the light-conducting element, between the end and the reflective surface. There is no way that its presence would prevent reflection, or Coleman would not have placed it there.

Applicant also argues that Coleman does not disclose the lancet having an opening enabling the test field to protrude beyond the lancet tip. The Examiner again disagrees. Coleman clearly has an opening. Applicant has not claimed the test field actually protruding beyond the tip, merely the presence of an opening that would allow such an occurrence to take place. Since Coleman has the opening, the theoretical protrusion is therefore enabled, since all Applicant requires is the opening.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5586553 to Halili, 7654956 to Brister, 5390671 to Brister, 2004/0133164 to Funderburk, 5568806 to Cheney, and 5425717 to Mohiuddin, which all disclose analysis systems where a sensor protrudes beyond the tip of a lancet after insertion.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735